JUN 2 2 2001

510(k) Summary of Safety and Effectiveness
510(k) Number K010990

AMS Sling Fixation System

Date:	April 2, 2001
Submitter:	American Medical Systems, Inc. 10700 Bren Road West Minnetonka, MN 55343 Tel: 952-933-4661 Fax: 952-930-6157
Contact:	Avraham Biran / Elsa Linke
Trade Name:	AMS Sling Fixation System
Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue
Class:	II
Predicates:	Influence In-Fast Bone Screw System, K970292 Bioelectron CurvTek TSR System, K972860

Description of Device
The device is intended for soft tissue fixation to bones in the pelvic region (e.g., pubic, sacral, etc.) by means of bone screws threaded with suture. It consists of a drill threaded with suture.

Intended Use
The *AMS Sling Fixation System* is intended for soft tissue fixation to the pubic bone by means of a suture threaded through the bone. It is indicated for use during surgical procedures where soft tissue fixation to bones in the pelvic region is needed, such as bladder neck suspension and vaginal sling procedures for female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Technological Characteristics
The design and materials as well as the intended use and indications of the AMS Sling Fixation System and *In-Fast* systems are substantially equivalent. The only difference is that the *In-Fast* system uses sutures that are attached to bone screws inserted into the bone, while the *AMS Sling Fixation System* uses sutures alone. The intended use and subset of the indications are substantially equivalent also between the *AMS Sling Fixation System* and *CurvTek* TSR System.

Information and performance testing provided and referenced in the application demonstrates equivalence to the predicate devices with respect to intended use, labeling and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2001

Ms. Elsa A. Linke
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K010990
Trade/Device Name: AMS Sling Fixation System
Regulation Number: 878.5010, 878.4820
Regulatory Class: II
Product Code: GAW, KIJ
Dated: April 2, 2001
Received: April 3, 2001

Dear Ms. Linke:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K010990

Device Name: *AMS Sling Fixation System*

Indications for Use: The *AMS Sling Fixation System* is intended for soft tissue fixation to the pubic bone by means of a suture threaded through the bone. It is indicated for use during surgical procedures where soft tissue fixation to bones in the pelvic region is needed, such as bladder neck suspension and vaginal sling procedures for female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-off)
Division of General and Restorative Devices

510(k) Number _____

Prescription Use _____ OR Over the Counter Use_____
(Per 21 CFR 801.109)

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010990